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| 09/992,491      | 11/21/2001  | Gary S. Hahn         | 270/058             | 9928             |

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| EXAMINER |
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WELLS, LAUREN Q

| ART UNIT | PAPER NUMBER |
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1617

DATE MAILED: 05/27/2003

17

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/992,491

Applicant(s)

HAHN ET AL.

Examiner

Lauren Q Wells

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 3/7/03.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-65 is/are pending in the application.
- 4a) Of the above claim(s) 2,4-25,28-32,41 and 46-65 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) 1,3,26,27,33-40 and 42-45 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 14. 6) ☐ Other: \_\_\_\_\_

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### **DETAILED ACTION**

Claims 1-65 are pending. Claims 2, 4-25, 28-32, 41, and 46-65 are withdrawn from consideration, as they are directed toward non-elected subject matter.

The Amendment filed 11/21/01, amended the first paragraph of the specification, deleted attorney docket numbers from pages 22 and 31 of the specification, and added a brief description of the drawings.

The Amendment filed 8/19/02, Paper No. 6, amended claim 1.

#### ***Priority***

Upon a review of the parent Applications of the instant application, the instant application is afforded the priority date of 6/20/96, Application No. 08/666,978.

#### ***Election/Restrictions***

Applicant's election with traverse of the Election/Restriction Requirement in Paper No. 7 is acknowledged. The traversal is on the ground(s) that "a complete search of the art relative to 5-10% divalent strontium cation in a particular topical vehicle would necessarily include a search of the other topical vehicles and would in no way be unduly burdensome". This is not found persuasive. The Examiner respectfully points out the instant composition comprises many more ingredients in addition the strontium cation and the vehicle. Furthermore, the instant composition can comprise many different composition forms. A search of every single possible combination of possible ingredients and cosmetic forms would be burdensome.

The requirement is still deemed proper and is therefore made FINAL.

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A call to Diane Gardner on 4/17/03, clarified the Election response filed 3/7/03, Paper No. 16. Alpha-hydroxy acids were elected as the irritant agents, polysorbate 60 was elected as the surfactant, and lotion was elected as the cosmetic form.

### ***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claim 1 is provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 62, 64-66, 68-69 of copending Application No. 10/189344. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant invention teaches their composition as comprising 0.5-10% of an aqueous-soluble divalent strontium cation and '344 teaches their composition as comprising at least about 50mM of aqueous-soluble divalent cation.

However, it would have been obvious to one of ordinary skill in the art at the time the invention was made to teach the percent weights in the instant invention in that of '344 because it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233.

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This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 3, 26-27, 33-40, 42-45 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The phrase "wherein said topical formulation is packaged with instructions directed the administration of said compositions to the skin of an animal subject" is new matter, as it is not recited in the original disclosure.

Claims 1, 3, 26, 27, 33-40, 42-45 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for reducing skin irritation, does not reasonably provide enablement for preventing skin irritation. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

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The factors to be considered in determining whether a disclosure meets the enablement requirement of 35 U.S.C. 112, first paragraph, have been described in *In re Wands*, 8 USPQ2d 1400 (Fed. Cir. 1988). Among these factors are: (1) the nature of the invention; (2) the state of the prior art; (3) the relative skill of those in the art; (4) the predictability or unpredictability of the art; (5) the breadth of the claims; (6) the amount of direction or guidance presented; (7) the presence or absence of working examples; and (8) the quantity of experimentation necessary. When the above factors are weighed, it is the examiner's position that one skilled in the art could not practice the invention without undue experimentation.

(1) The nature of the invention:

The invention provides a composition comprising 0.5-10% of an aqueous-soluble divalent strontium cation, and a suitable topical formulation vehicle, wherein said composition is effective to prevent or reduce skin irritation at the skin site where the formulation is administered.

(2) The state of the prior art

The state of the prior art teaches that it is known to treat/reduce skin irritation comprising topically applying the skin a composition comprising an aqueous-soluble divalent strontium cation and a suitable topical vehicle. However, the art does not teach preventing skin irritation with such a composition. See US 4,943,432; 4,477,439; and 4,191,750.

Preventing skin irritation is inconsistent with what is known in the art since (1) reduction of skin irritation indicates that irritation is decreased, but not prevented; and (2) elimination of skin irritation indicates that symptoms of skin irritation may occur. Furthermore, prevention of skin irritation indicates that the subject never experiences any characteristics associated with skin irritation. Hence, the amount of guidance present in the specification, the absence of data indicating that the symptoms of skin irritation do not occur when strontium salts are administered, and the state of the prior art indicating that the treatment using strontium salts in composition is possible, all indicate that treatment, not prevention of skin irritation is possible.

(3) The relative skill of those in the art

The relative skill of the those in the art is high.

(4) The predictability or unpredictability of the art

The art is predictable, as it is well established in the art how to treat skin irritation with compositions comprising strontium salts.

(5) The breadth of the claims

The claims are very broad, as the composition can comprise any ingredients as long as a strontium salt and vehicle are present.

(6) The amount of direction or guidance presented

The specification exemplifies compositions for inhibiting/reducing skin irritation. However, the specification provides no guidance regarding compositions that prevent skin irritation.

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(7) The presence or absence of working examples

While the instant specification provides numerous exemplifications of the instant compositions, it fails to provide any examples that prevent skin irritation, as all the examples are directed to inhibiting/reducing skin irritation.

(8) The quantity of experimentation necessary

One of ordinary skill in the art would be burdened with a burdensome quantity of experimentation to determine what compositions prevent skin irritation, as the compositions of the instant invention can comprise an incredible number of additives in different amounts and combinations. Thus, when the above factors are weighed together, one of ordinary skill in the art would be burdened with undue "painstaking experimentation study" to determine the all of the instant compositions which prevent skin irritation.

This rejection can be overcome by deleting the term "prevent" in claim 1 (line 5).

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 1 is rejected under 35 U.S.C. 103(a) as being unpatentable over Biener (4,943,432).

The instant invention is directed toward a composition comprising 0.5-10% aqueous soluble divalent strontium cation and a suitable topical vehicle.

Biener teaches a salt mixture comprising strontium for the treatment of psoriasis and other skin diseases (abstract). The salt mixture contains from 0.02-10.55/kg strontium ion (col. 2, line 32). Water is taught as a medium (col. 3, lines 53-55). Additional ingredients that may be in the composition are salicylic acid (an anti-acne agent/beta-hydroxy acid), emollients, etc (col. 3, lines 38-44), natural and synthetic gums and colloids (col. 4, lines 9-15) and glycol (col. 4,

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lines 21). For preservatives, see column 5, line 29. The reference lacks an exemplification of the percent weight of strontium.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to teach the strontium as comprising 0.5-10% of the composition because it is taught that strontium can comprise 0.02-10.5g/kg of the salt mixture and it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. In *re Aller*, 105 USPQ 233.

The Examiner respectfully points out that the recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In a claim drawn to a process of making, the intended use must result in a manipulative difference as compared to the prior art. See *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963). The Examiner respectfully points out that the intended use of the instant claims is not given patentable weight. The phrases “for reducing skin irritation in animals”, “wherein said topical formulation is packaged with instructions directing the administration of said composition to the skin of an animal subject”, and “effective to prevent or reduce skin irritation at the skin site where the formulation is administered” is considered as the intended use of the composition.

The Examiner respectfully points out that the limitations in the instant independent claims regarding the properties of the compositions are not given patentable weight, as a



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composition comprising the same components must have the same properties, i.e., reducing skin irritation.

Claims 3, 26, 33-38, 42 are rejected under 35 U.S.C. 103(a) as being unpatentable over Biener (4,943,432) as applied to claim 1 above, and further in view of D'Alelio (4,477,439).

Biener is applied as discussed above. The reference fails to teach a lotion and surfactants.

D'Alelio teaches a composition for reducing soreness of irritated skin comprising strontium. The formulation can be in the form of a powder, an aqueous suspension, a paste, an ointment, or a cream (see abstract). Additional ingredients are viscosity modifiers, dispersing agents (surfactants), preservatives, and anesthetics (col. 1, lines 49-51). Colorants and perfumes are disclosed at column 2, line 6. For anionic surfactants, see column 1, lines 59-63.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to teach the composition of Biener in the form of a lotion, as taught by D'Alelio, because Biener teaches his compositions in the form of an aqueous solution, a gel, a salve, and a powder, and D'Alelio teaches powders, aqueous suspensions, ointments (salves), and creams (lotions) as interchangeable cosmetic forms for compositions comprising strontium; thus, one of skill in the art would be motivated to teach the composition of Biener in the form of a lotion (cream) because D'Alelio teaches aqueous solutions, salves, powders, and creams (lotions), as interchangeable.

Claims 39-40 are rejected under 35 U.S.C. 103(a) as being unpatentable over Biener in view of D'Alelio as applied to claims 1, 3, 26, 33, 34, 35, 37, 38, 42 above, and further in view of Yu et al. (2001/0016604).

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Biener and D'Alelio are applied as discussed above. The references do not teach alpha-hydroxy acids.

Yu et al. teach additives enhancing topical actions of therapeutic agents. Hydroxy acids are taught as substantially enhancing the therapeutic efficacy of cosmetic and pharmaceutical agents in topical treatment of cosmetic conditions, dermatologic disorders or other afflictions. Specifically, lactic acid and glycolic acid are taught as normalizing the disturbed keratinization in psoriasis. See [0008], [0136]-[139].

It would have been obvious to one of ordinary skill in the art at the time the invention was made to add glycolic acid, as taught by Biener, to the composition of Yu et al. because of the expectation of achieving a composition that synergistically treats psoriasis by normalizing the disturbed keratinization in psoriasis.

Claims 27, 42-45 are rejected under 35 U.S.C. 103(a) as being unpatentable over Biener in view of D'Alelio as applied to claims 1, 3, 20, 33, 34, 35, 37, 38, 42 above, and further in view of McAtee (5,665,364).

Biener and D'Alelio are applied as discussed above. The references do not teach polysorbate 60 (Applicant's elected surfactant species) or emulsifiers.

McAtee teaches compositions for topical delivery of active ingredients. Emulsifiers are taught as useful for emulsifying the various carrier components of the topical cosmetic compositions. Nonionic, cationic, anionic, and zwitterionic emulsifiers, and combinations thereof, are taught as suitable emulsifiers that can be added to the composition. Polysorbate 60 is specifically taught as a preferred emulsifier. See Col. 16, line 63-Col. 17, line 31.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to add polysorbate 60, as taught by McAtee, to the composition of the combined references because of the expectation of achieving a composition that effectively emulsifies the various carrier components of the composition.


***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lauren Q Wells whose telephone number is (703) 305-1878. The examiner can normally be reached on M-F (7-5:30), with alternate Mondays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on (703)305-1877. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9306 for regular communications and (703) 872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1234.

lqw  
May 5, 2003

  
SREENI PADMANABHAN  
PRIMARY EXAMINER

5/4/03